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Center for Drug Evaluation and Research (HFD006)
Food and Drug Administration
560 Fishers Lane
Rockville, MD 20857

RE; Risk Management of Prescription Drugs

Dear Ms Bechtel,

I attended, via teleconference, you recent meeting on May 22,2002 about risk management of prescription drugs. I found it interesting but could not stay in the afternoon for the other speakers and missed what some referred to as firework with the early speakers due to traffic. Nonetheless, I thought I would send you some comments about this topic, which is quite familiar to me since I have spent the last 37 years of my career working for drug companies in clinical research/medical affairs and the last **8** in Drug Safety.

The good will of the FDA/CDER staff to help correct a really difficult problem is admirable but the real efforts should come from the medical profession at large and more specifically from the school of medicine who do not offer enough training in ADVERSE drug Reaction RECOGNITION.

Despite rigid protocols, adequate monitoring and surveillance, while a drug is being developed, the drug companies have a hard time getting the right information they need from the investigators doing clinical trials about Adverse Drug Reactions and Serious Adverse Drug Reaction. There are conscientious investigators who take this task seriously but they are not numerous. Most have their research nurse fill in the form and answer questions the company MD has for them.

Once the drug is on the market, the situation gets worse. The new drug on the block gets immediate attention and prescriptions flow fast and furiously from the pen of practitioners. However, the knowledge of adverse event only seems to sink in when the physicians have a patient complaining about it or when one of their patients ends up in the hospital. If there are contraindications, warning, precautions, such as is found in the package insert, many will be careful and observe them, but not all. How come then that the number of SAEs is not decreasing despite all the reporting that the drug companies do? Despite your sustained efforts at informing the physicians, nurses, and the public at large, the numbers of patients that get harmed by drug SAEs continue to grow. This situation was the reason for your seminar in an attempt to characterize such risks in a better and more effective way.

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The most important person in the doctor-patient relationship is the patient, irrespective of what the physicians say and the patients are almost always shunted aside by the lack of

adequate education about drugs by their physicians. Thus the very time when the education would be best served to a patient, during a consultation, is not taking place. Secondly, if the patient has an Adverse Event, he/she and the doctor as well, do not seem to differentiate the AE manifestations from the disease manifestations. As a consequence, the AE is not recognized, it is not treated and the dangers of prescription drugs continue to flourish. Thirdly, most practitioners of medicine (and surgeons as well but to a lesser extent) practice poly-pharmacy. As a consequence of this, drug interactions multiply. My record, from memory, is the case of a patient who had 43 concomitant medications and ended up in the hospital because she was confused, dizzy, fell, broke her hip, was operated on, developed a deep vein thrombosis, a pulmonary embolism and died a few days later.

Now to me that's scary. As a patient, I am scared stiff that, one day, one of my doctors will doom me. Fortunately for me, being a physician and a clinical pharmacologist, I can protect myself, something the great majority of patients cannot do. Even then, I am not above risks. Recently, my internist phoned me to tell me that my LFTs were out of whack (SGOT 1200, SGPT 1500, Alkaline Phosphatase 450, bilirubin 0.78). He told me to stop ZOCOR forever. I shudder at the thought that I could have postponed my visit by a week or two and find myself getting up in the morning looking like a Chinese. And I am a Smarter Patient! Pity the poor souls who run to doctor's office daily across the nation not knowing what could happen to them

Recently, CERT issued an article in CPT about the lack of knowledge among residents and physicians concerning SAE. Only **8 %** were aware of the Institute of Medicine's report: "To Err is human." Not only is it human it is criminal.

I believe that the FDA, the medical press, the medical associations, the drug companies, the pharmacists, the nurses communicate about the risks of prescription drugs well enough but obviously this is not sufficient. More communications does not mean that they will be read. What should be done?

This is a vast enterprise that will require an overhaul of the way medicine is thought in schools of medicine, and how medicine is practiced. It will require the development of educational programs in high schools and college, in adult education, about drugs and their dangers. This is essentially what I describe in my book, recently published, "The Smarter Patient Knows Better" (Dorrance Publishers Inc.).

I enclose a copy for your review and direct you to Parts 3 and 4 where I discuss the problems and the solutions. I have no magic solutions unfortunately. Maybe some of the comments I made here will be useful in helping the FDA address this very dangerous situation, a situation that is not limited to the US. It is a global issue and the WHO is trying also to address it across the nations.

In conclusion until we turn to the patients, and educate them about their body functions and how their body works, until we educate patients about their disease and their treatments, until we educate patients to recognize adverse drug reactions and be on the

look out for them, the present situation will not change. We have ignored patients long enough. It is time that we consider them as full partners in the healthcare fields, and give them the tools to make them take their responsibilities for their health maintenance, rather than dump these on the shoulders of an all ready overburdened profession.

Hope you will have a nice reading.

Sincerely,

Lucien Joubert

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